



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1936]

Electronic Cigarettes and the Public Health; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; extension of comment period.

The Food and Drug Administration (FDA), Center for Tobacco Products, is announcing a public workshop to obtain information on electronic cigarettes (e-cigarettes) and the public health. This will be the final in a series of three workshops. The workshop will include presentations and panel discussions about the current state of the science and will focus on impacts on the population as a whole, including users and non-users of tobacco products.

Dates and Times: The public workshop will be held on June 1 and 2, 2015. Individuals who wish to attend the public workshop must register by May 20, 2015.

Location: The public workshop will be held at the Marriott Inn and Conference Center, University of Maryland University College, Potomac Ballroom, 3501 University Blvd. East, Hyattsville, MD 20783. The conference center's telephone number is 301-985-7300.

Contact Person: Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, rm. G335, Silver Spring, MD 20993-0002, 1-877-287-1373, email: [workshop.CTPOS@fda.hhs.gov](mailto:workshop.CTPOS@fda.hhs.gov).

Registration to Attend the Workshop: If you wish to attend the workshop in person or by Webcast, you must register by submitting an electronic or written request no later than May 20, 2015. Please submit electronic requests at <https://www.surveymonkey.com/s/CTP-June-Workshop>. Persons without Internet access may send written requests for registration to Caryn Cohen (see Contact Person). Requests for registration must include the prospective attendee's name, title, affiliation, address, email address if available, and telephone number. Registration is free and you may register to attend in-person or view the live Webcast. Seating and viewership are limited, so early registration is recommended. FDA may limit the number of registrants from a single organization and the total number of participants if registration reaches full capacity. For registrants with Internet access, confirmation of registration will be emailed to you no later than May 25, 2015. Onsite registration may be allowed if space is available. If registration reaches maximum capacity, FDA will post a notice closing registration at <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm>.

If you need special accommodations due to a disability, please contact Caryn Cohen (see Contact Person) at least 7 days in advance of the meeting.

Presenters and Panelists: FDA is interested in gathering scientific information from individuals with a broad range of backgrounds on the scientific topics to be discussed at the workshop. To be considered as a presenter, please provide the following:

- A brief abstract for each presentation. The abstract should identify the specific topic(s) to be addressed and the amount of time requested.
- A one-page biosketch that describes and supports the speaker's scientific expertise on the specific topic(s) being presented, nature of the individual's experience and research in the scientific field, positions held, and any program development activities.

Panelists will discuss their scientific knowledge on the questions and presentations in each session. To be considered to serve as a panelist, please provide the following:

- A one-page biosketch that describes and supports the speaker's scientific expertise on the specific topic(s) being presented, nature of the individual's experience and research in the scientific field, positions held, and any program development activities.

If you are interested in serving as a presenter or panelist, please submit the requested information, along with the topic on which you would like to speak, to [workshop.CTPOS@fda.hhs.gov](mailto:workshop.CTPOS@fda.hhs.gov) by April 3, 2015.

Oral Presentations by Members of the Public: This workshop includes a public comment session. Persons wishing to present during the public comment session must make this request at the time of registration and should identify the topic they wish to address from among those topics under consideration that are identified in section III. FDA will do its best to accommodate requests to present. FDA urges individuals and organizations with common interests to consolidate or coordinate their comments, and request a single time for a joint presentation. For those requesters with Internet access, Caryn Cohen (see Contact Person) will email you regarding your request to speak during the public comment period by May 25, 2015.

Transcripts: A transcript of the proceedings will be available after the workshop at <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm> as soon as the official transcript is finalized. It will also be posted to the docket at <http://www.regulations.gov>.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing a public workshop to gather scientific information and stimulate discussion among scientists about electronic cigarettes (e-cigarettes). The focus of this

workshop will be the impact of e-cigarettes on population health, including prevalence and patterns of use, impacts of e-cigarettes on tobacco product users and non-users, and knowledge, attitudes, and beliefs about e-cigarette products. A workshop on December 10-11, 2014, focused on e-cigarette product science, product packaging, constituent labeling, and environmental impact; and a workshop on March 9-10, 2015, focused on the impact of e-cigarettes on individual health.

On April 25, 2014, FDA published a document to extend its tobacco product authorities to additional products that meet the statutory definition of "tobacco product" entitled "Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products" (79 FR 23141, April 25, 2014, Docket No. FDA-2014-N-0189) (proposed deeming rule). If the proposed deeming rule is finalized as proposed, e-cigarettes that are tobacco products would be subject to FDA regulation under Chapter IX of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 387-387u). As stated in the proposed deeming rule, FDA "is aware of the recent significant increase in the prevalence in e-cigarette use" (79 FR 23141 at 23152), and there is much to be learned about these relatively new entrants to the market.

These workshops are intended to better inform FDA about these products. Should the Agency move forward as proposed to regulate e-cigarettes, additional information about the products would assist the Agency in carrying out its responsibilities under the law. This would be true regardless of the details of any such final rule. Accordingly, FDA is working to obtain such information now rather than waiting for the conclusion of the deeming rulemaking.

Participants should note that this workshop is not intended to inform the Agency's deeming rulemaking. All comments regarding the proposed deeming rule were to be submitted to the Agency by August 8, 2014 (Docket No. FDA-2014-N-0189). As such, the scope of this workshop is limited to the topics presented in section III.

## II. Extension of Comment Period

Extension. At the start of the first workshop in this series, FDA announced via a Federal Register document the opening of a docket for submission of written comments regarding all three workshops (see Establishment of a Public Docket; Electronic Cigarettes and the Public Health Workshop, Docket No. FDA-2014-N-1936, <http://www.gpo.gov/fdsys/pkg/FR-2014-12-02/pdf/2014-28261.pdf>). The comment period for submission of written comments was scheduled to end on April 15, 2015. The Agency is extending the comment period to end on July 2, 2015, to allow interested parties time to submit comments concerning the third workshop.

General Information About Submitting Comments. Regardless of attendance at the public workshop, interested parties are invited to submit comments, supported by research and data, regarding e-cigarettes and the public health. Information related to workshop presentations and discussion topics, including specific questions to be addressed at the workshop, can be found at <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm>.

Interested persons may submit either electronic comments to <http://www.regulations.gov> or written comments to this docket to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Comments

submitted to the docket will not be added to other dockets, such as the docket for the proposed rule deeming additional tobacco products subject to the FD&C Act.

Public Availability of Comments. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>. As a matter of Agency practice, FDA generally does not post comments submitted by individuals in their individual capacity on <http://www.regulations.gov>. This is determined by information indicating that the submission is written by an individual, for example, the comment is identified with the category "Individual Consumer" under the field titled "Category (Required)," on the "Your Information" page on [www.regulations.gov](http://www.regulations.gov). For this docket, however, FDA will not be following this general practice. Instead, FDA will post on <http://www.regulations.gov> comments to this docket that have been submitted by individuals in their individual capacity. If you wish to submit any information under a claim of confidentiality, please refer to 21 CFR 10.20.

Information Identifying the Person Submitting the Comment. Please note that your name, contact information, and other information identifying you will be posted on <http://www.regulations.gov> if you include that information in the body of your comments. For electronic comments submitted to <http://www.regulations.gov>, FDA will post the body of your comment on <http://www.regulations.gov> along with your state/province and country (if provided), the name of your representative (if any), and the category identifying you (e.g., individual, consumer, academic, industry). For written submissions submitted to the Division of Dockets Management, FDA will post the body of your comments on <http://www.regulations.gov>, but you can put your name and/or contact information on a separate cover sheet and not in the body of your comments.

### III. Topics for Discussion

The public workshop will include presentations and panel discussion regarding e-cigarettes and the public health, specifically relating to the impact of e-cigarettes on the population as a whole. Topics to be addressed include: (1) Prevalence and patterns of use; (2) impacts on current tobacco product users; (3) impacts on non-users of tobacco products; and (4) knowledge, attitudes, beliefs, and perceptions about e-cigarette products.

Additional information related to workshop presentations and discussion topics, including specific questions to be addressed at the workshop, can be found at

<http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm>.

Dated: March 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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